OOTTO" 2EhO8h60

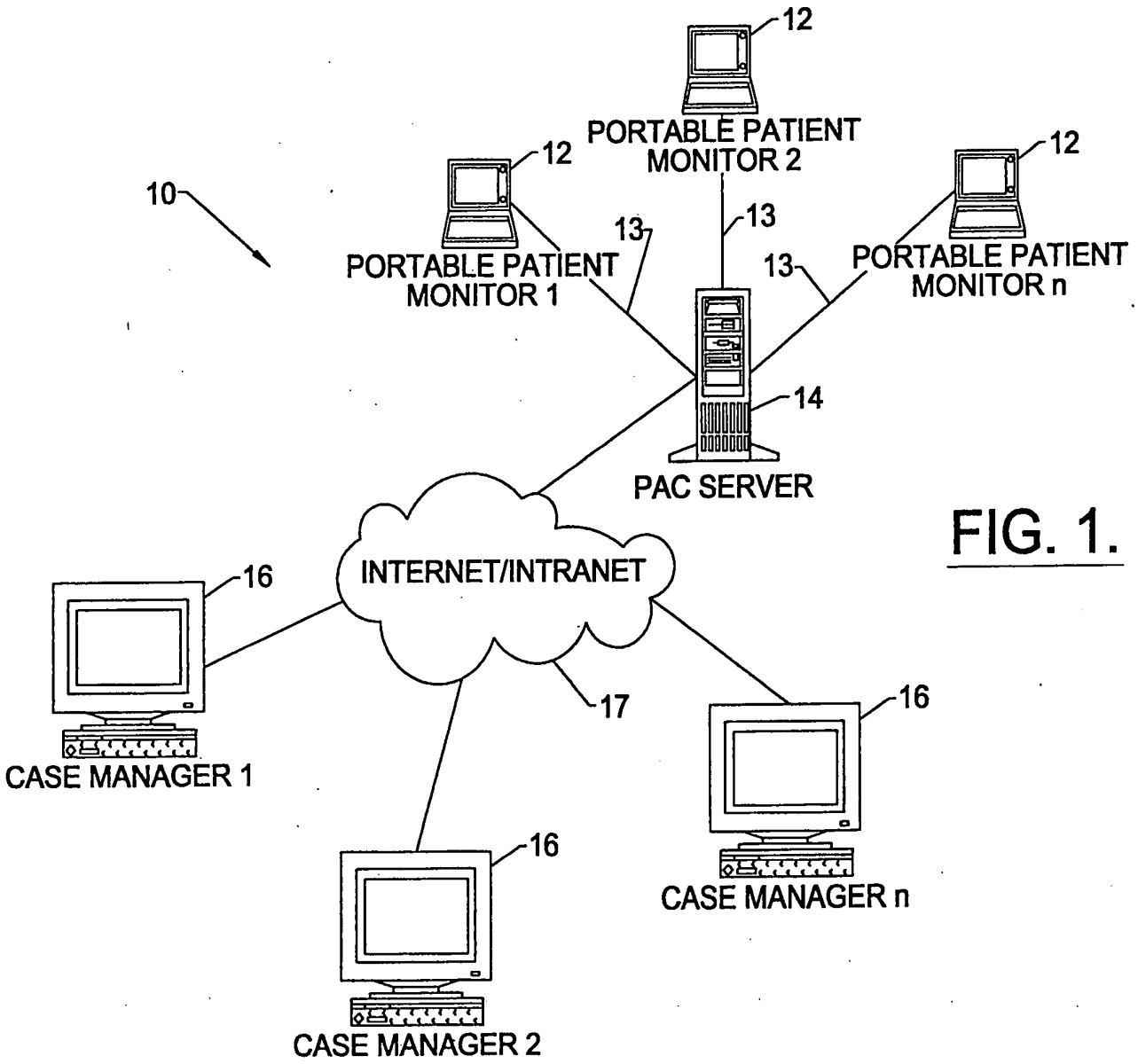


FIG. 1.

0074F0 "2340804"

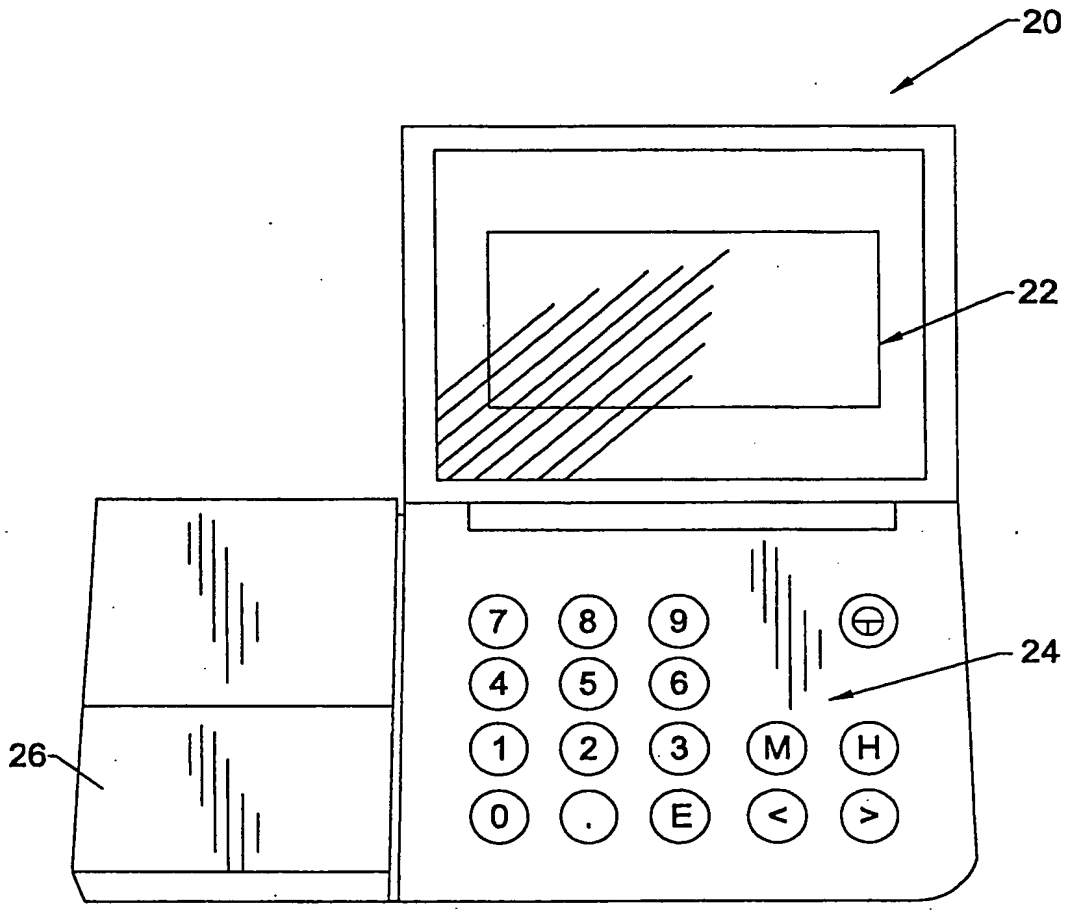


FIG. 2.

09463960 - 071700

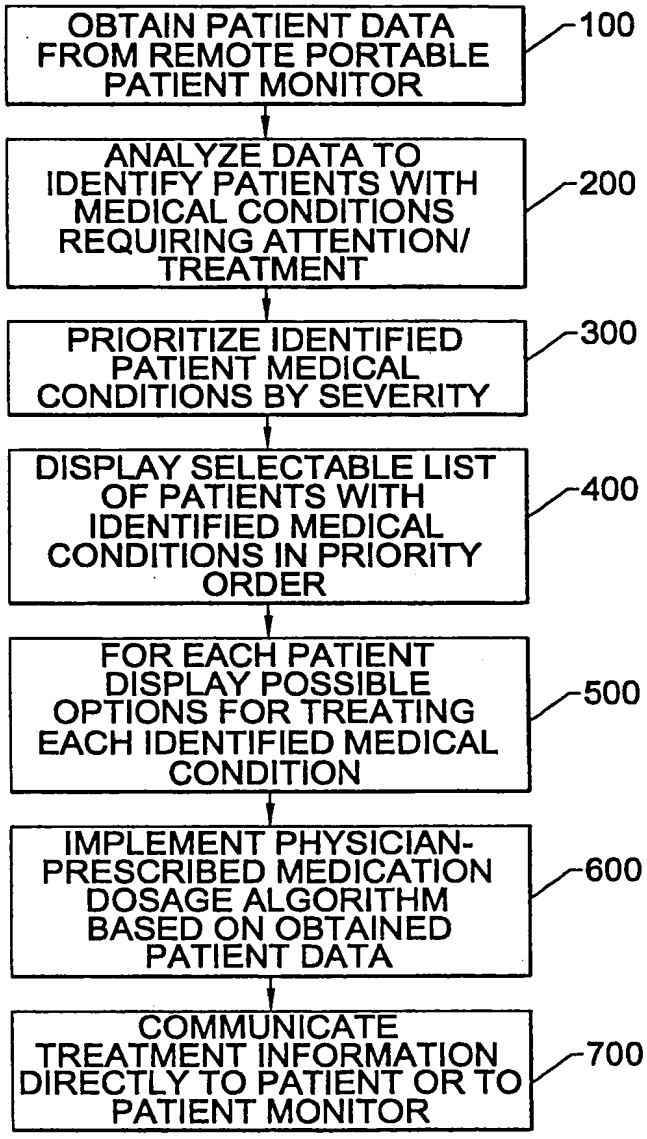


FIG. 3.

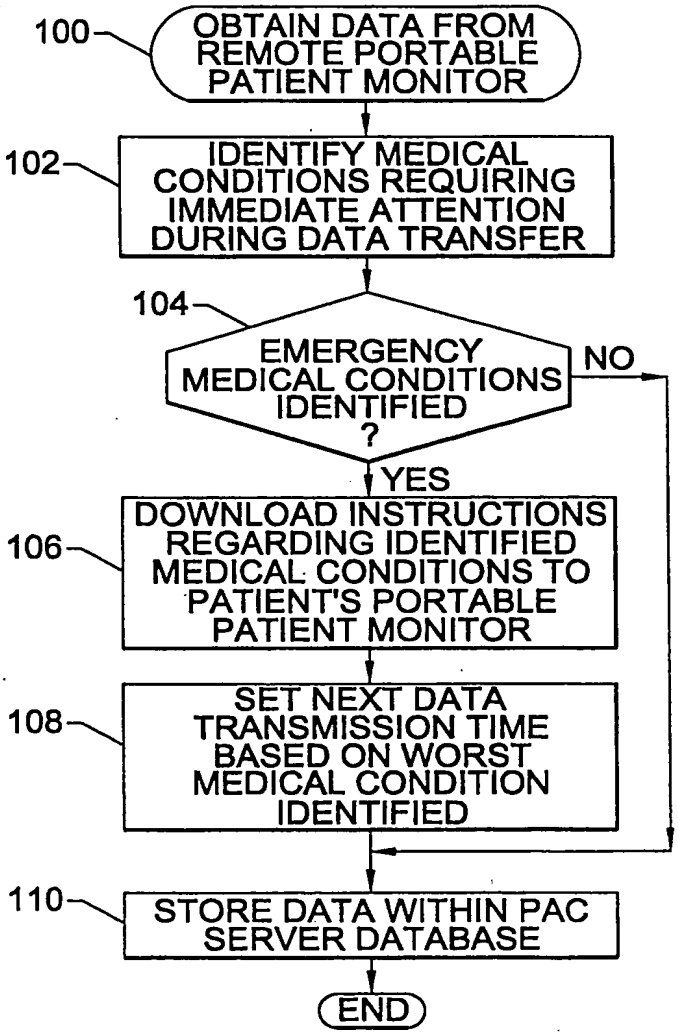

100
OBTAIN DATA FROM REMOTE PORTABLE PATIENT MONITOR
102
IDENTIFY MEDICAL CONDITIONS REQUIRING IMMEDIATE ATTENTION DURING DATA TRANSFER
104
EMERGENCY MEDICAL CONDITIONS IDENTIFIED ?
NO
YES
106
DOWNLOAD INSTRUCTIONS REGARDING IDENTIFIED MEDICAL CONDITIONS TO PATIENT'S PORTABLE PATIENT MONITOR
108
SET NEXT DATA TRANSMISSION TIME BASED ON WORST MEDICAL CONDITION IDENTIFIED
110
STORE DATA WITHIN PAC SERVER DATABASE
END

FIG. 4.

0014-0-2470804-0

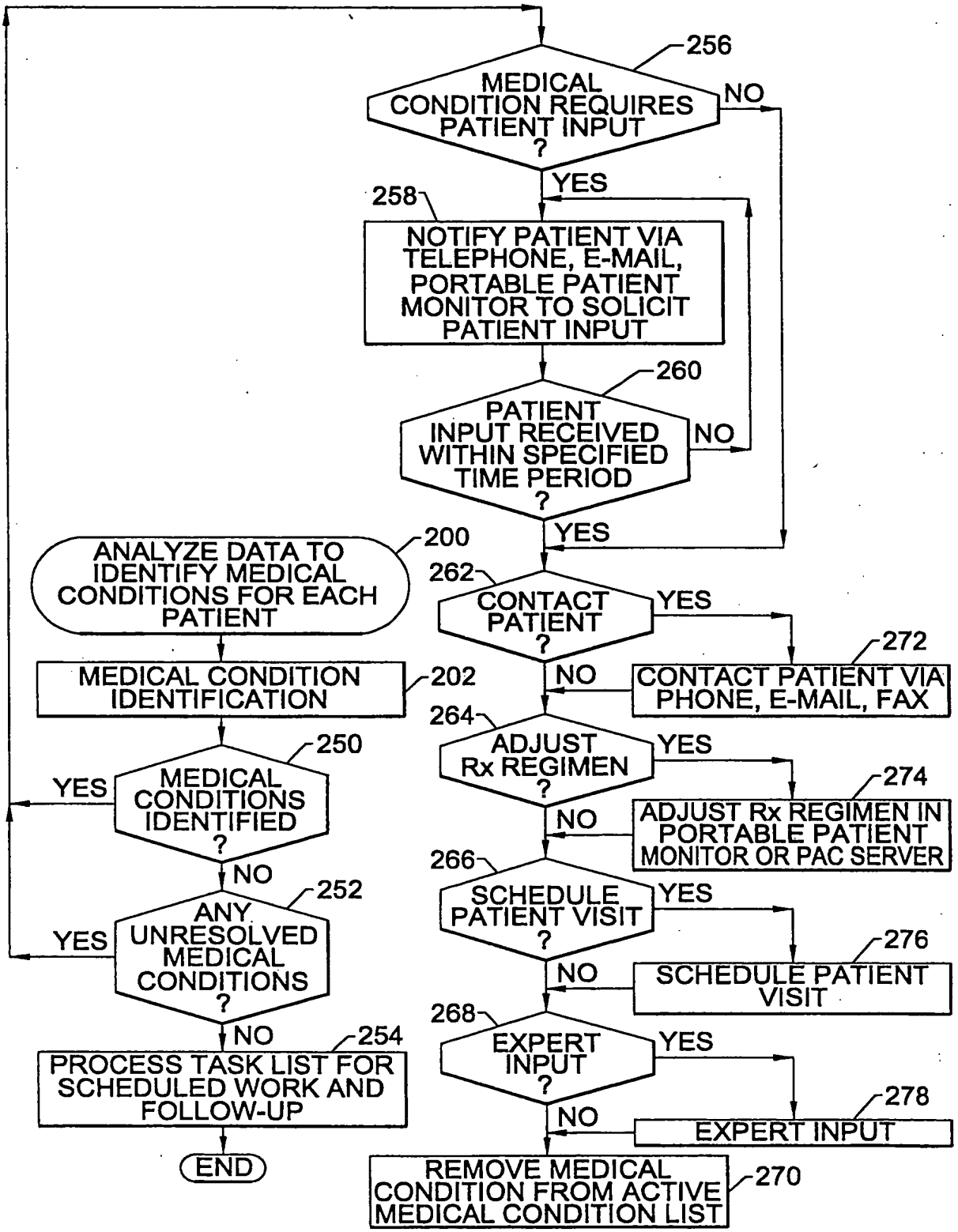


FIG. 5.

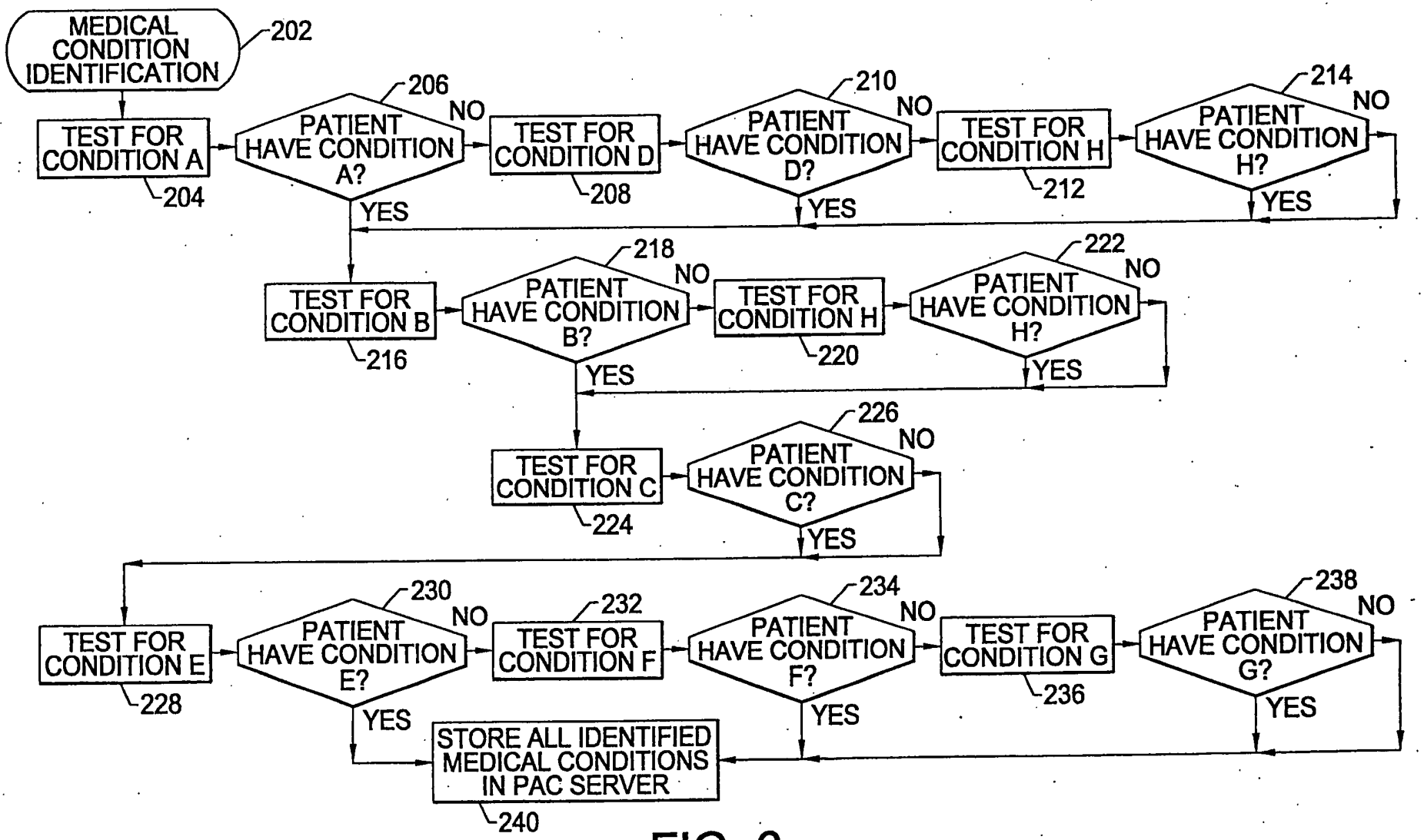

MEDICAL CONDITION IDENTIFICATION
202
TEST FOR CONDITION A
204
PATIENT HAVE CONDITION A?
206
NO
YES
TEST FOR CONDITION D
208
PATIENT HAVE CONDITION D?
210
NO
YES
TEST FOR CONDITION H
212
PATIENT HAVE CONDITION H?
214
NO
YES
TEST FOR CONDITION B
216
PATIENT HAVE CONDITION B?
218
NO
YES
TEST FOR CONDITION H
220
PATIENT HAVE CONDITION H?
222
NO
YES
TEST FOR CONDITION C
224
PATIENT HAVE CONDITION C?
226
NO
YES
TEST FOR CONDITION E
228
PATIENT HAVE CONDITION E?
230
NO
YES
TEST FOR CONDITION F
232
PATIENT HAVE CONDITION F?
234
NO
YES
TEST FOR CONDITION G
236
PATIENT HAVE CONDITION G?
238
NO
YES
STORE ALL IDENTIFIED MEDICAL CONDITIONS IN PAC SERVER
240

FIG. 6.

09490436 - 041700

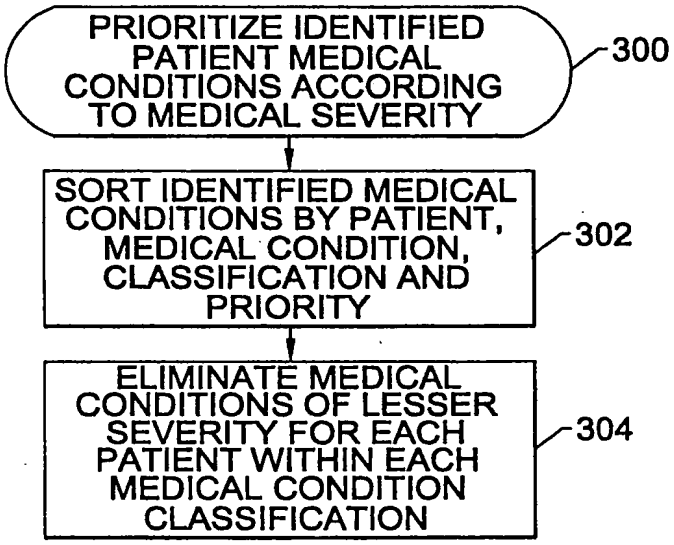


FIG. 7.

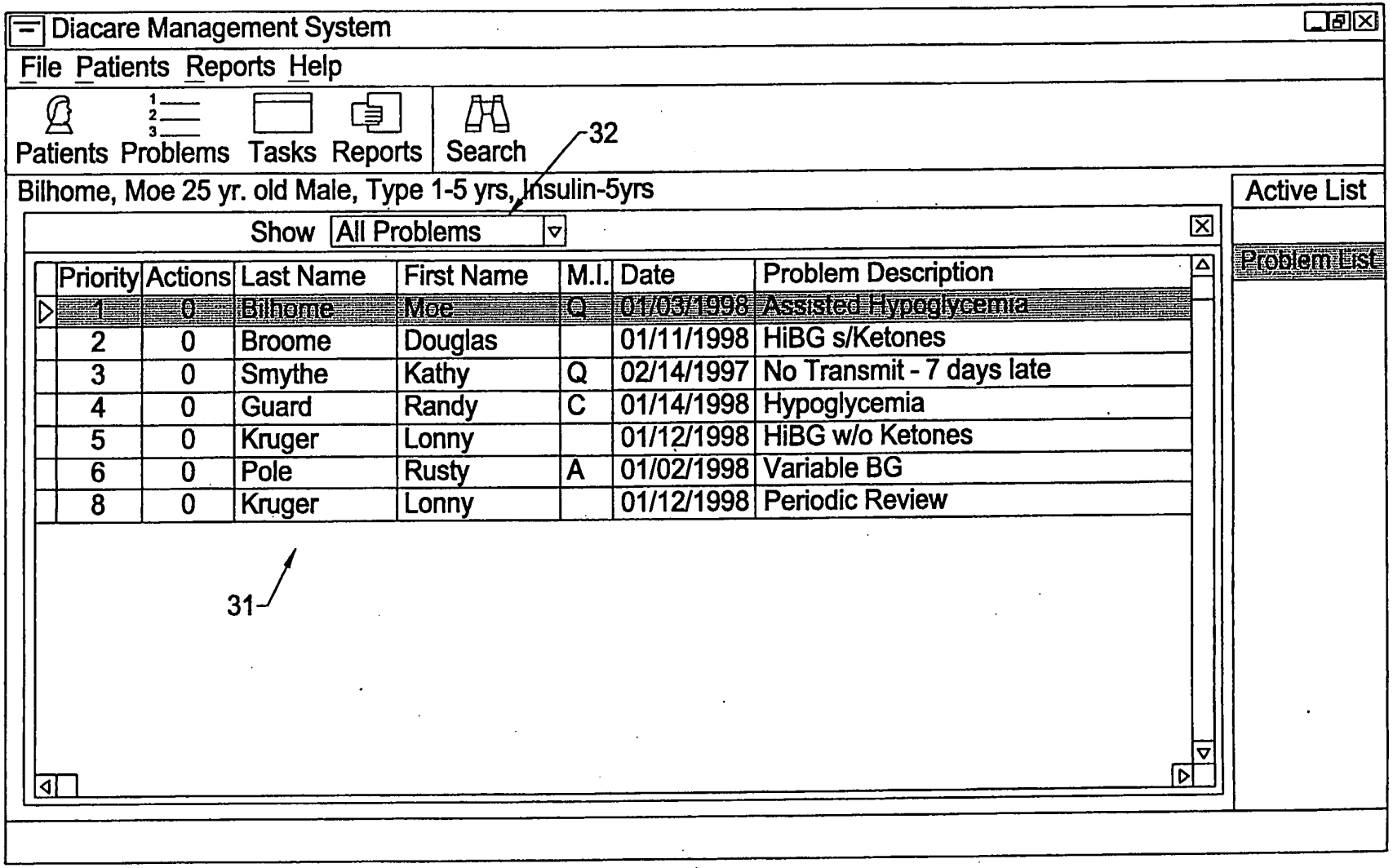

Diacare Management System
File Patients Reports Help
Patients
Problems
Tasks
Reports
Search
32
Bilhome, Moe 25 yr. old Male, Type 1-5 yrs, Insulin-5yrs
Active List
Show All Problems
Problem List
Priority Actions Last Name First Name M.I. Date Problem Description
1 0 Bilhome Moe Q 01/03/1998 Assisted Hypoglycemia
2 0 Broome Douglas 01/11/1998 HiBG s/Ketones
3 0 Smythe Kathy Q 02/14/1997 No Transmit - 7 days late
4 0 Guard Randy C 01/14/1998 Hypoglycemia
5 0 Kruger Lonny 01/12/1998 HiBG w/o Ketones
6 0 Pole Rusty A 01/02/1998 Variable BG
8 0 Kruger Lonny 01/12/1998 Periodic Review
31
30

FIG. 8.

OPTO-2608860

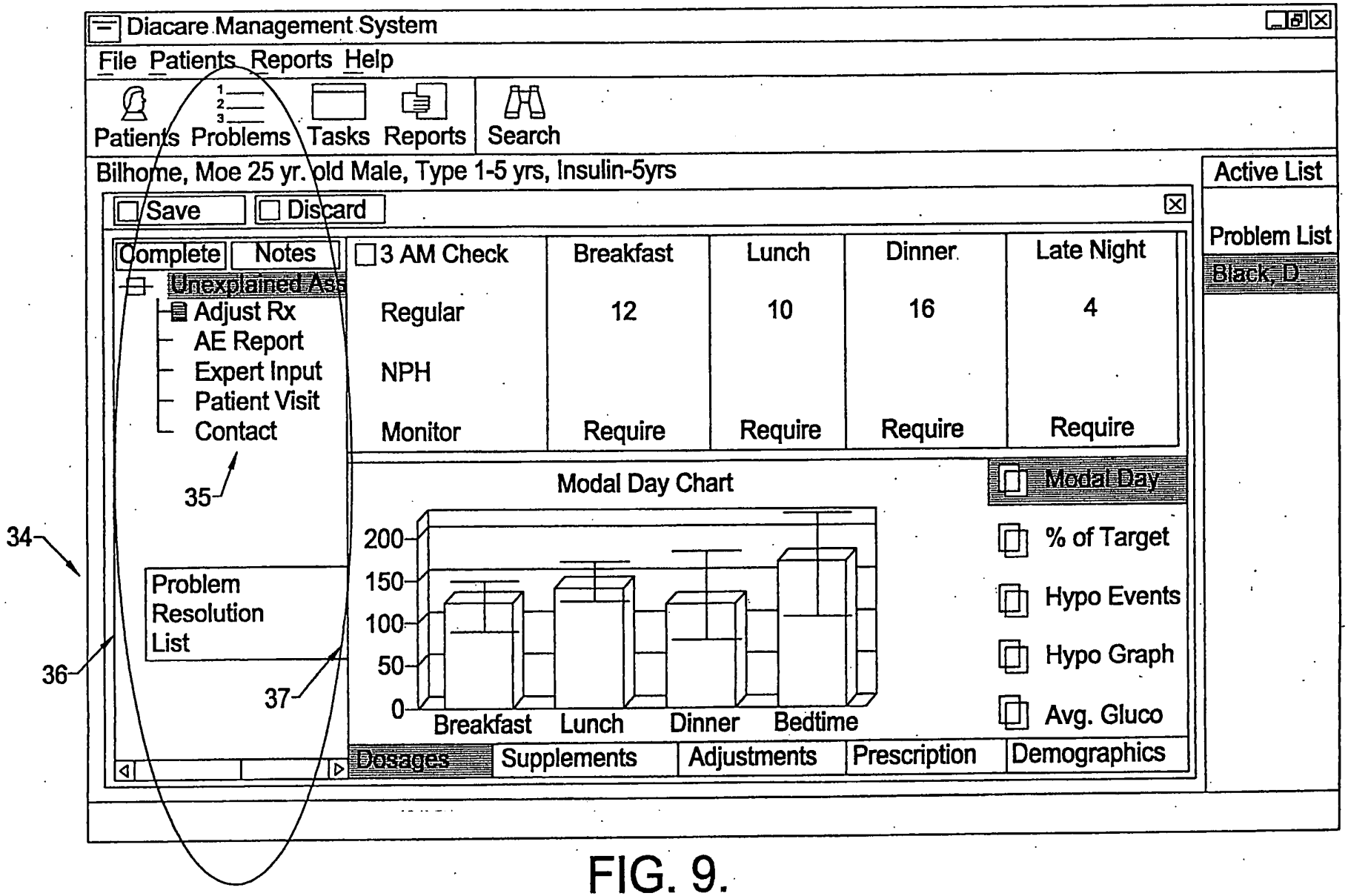


FIG. 9.

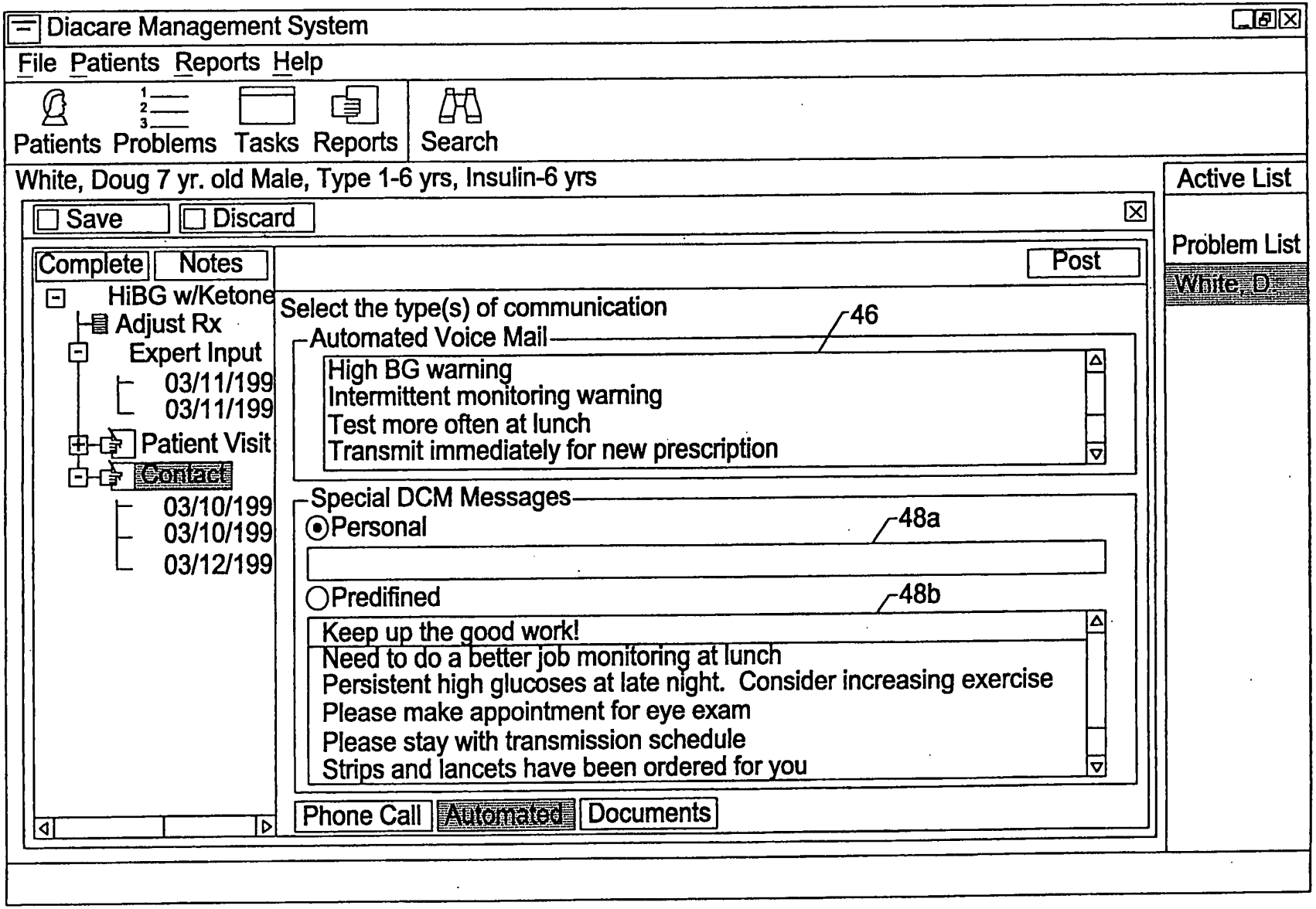

Diacare Management System
File Patients Reports Help
Patients
Problems
Tasks
Reports
Search
White, Doug 7 yr. old Male, Type 1-6 yrs, Insulin-6 yrs
Active List
Problem List
White, D
Save
Discard
Complete
Notes
Post
HiBG w/Ketone
Adjust Rx
Expert Input
03/11/199
03/11/199
Patient Visit
Contact
03/10/199
03/10/199
03/12/199
Select the type(s) of communication
46
Automated Voice Mail
High BG warning
Intermittent monitoring warning
Test more often at lunch
Transmit immediately for new prescription
Special DCM Messages
Personal
48a
Predifined
48b
Keep up the good work!
Need to do a better job monitoring at lunch
Persistent high glucoses at late night. Consider increasing exercise
Please make appointment for eye exam
Please stay with transmission schedule
Strips and lancets have been ordered for you
Phone Call
Automated
Documents
44a

FIG. 10A.

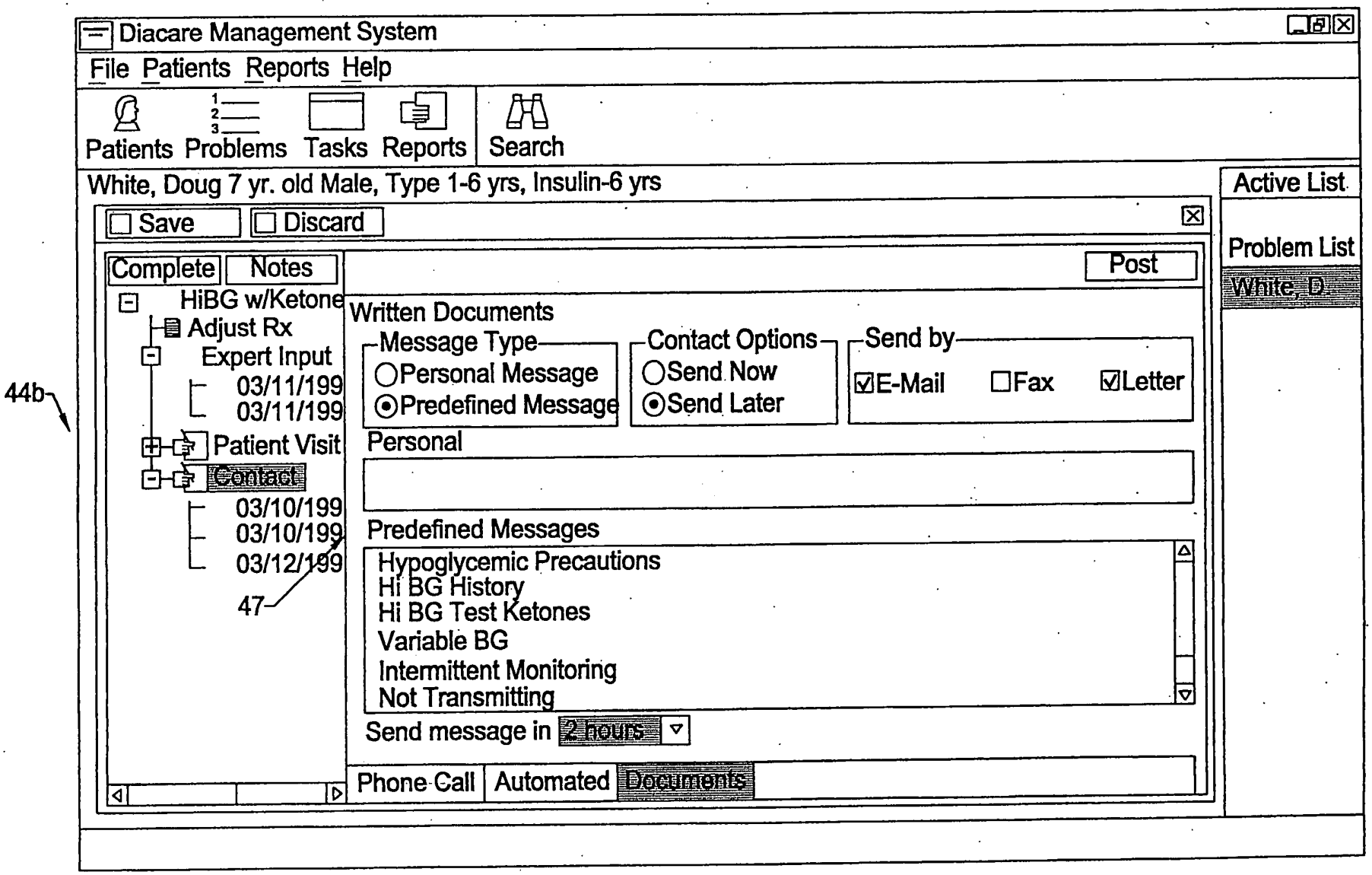

Diacare Management System
File Patients Reports Help
Patients
Problems
Tasks
Reports
Search
White, Doug 7 yr. old Male, Type 1-6 yrs, Insulin-6 yrs
Active List
Problem List
White, D.
Save
Discard
Complete
Notes
Post
HiBG w/Ketone
Adjust Rx
Expert Input
03/11/199
03/11/199
Patient Visit
Contact
03/10/199
03/10/199
03/12/199
47
44b
Written Documents
Message Type
Personal Message
Predefined Message
Contact Options
Send Now
Send Later
Send by
E-Mail
Fax
Letter
Personal
Predefined Messages
Hypoglycemic Precautions
Hi BG History
Hi BG Test Ketones
Variable BG
Intermittent Monitoring
Not Transmitting
Send message in 2 hours
Phone Call
Automated
Documents

FIG. 10B.

OUTTO "2EH08H60

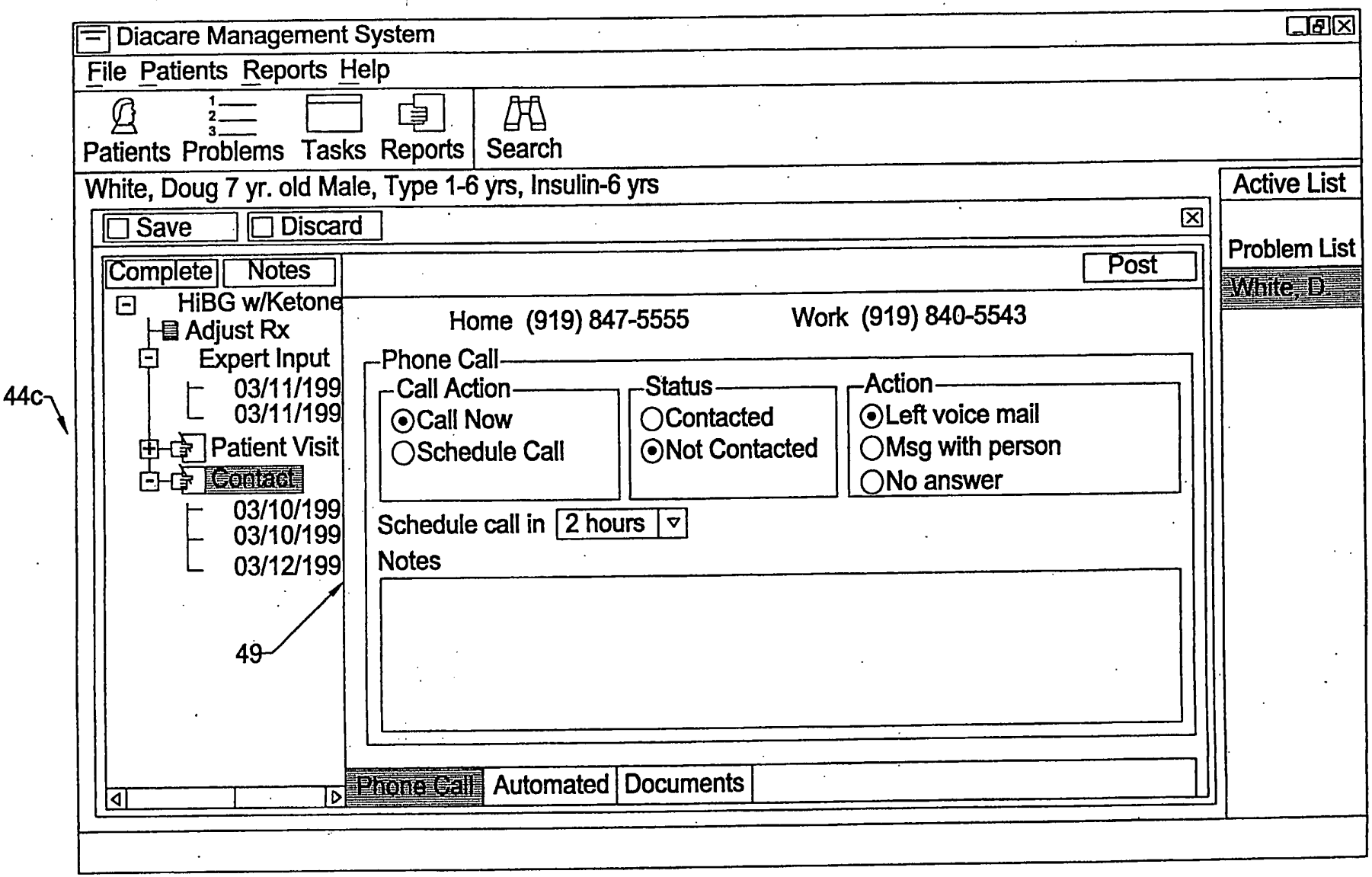


FIG. 10C.

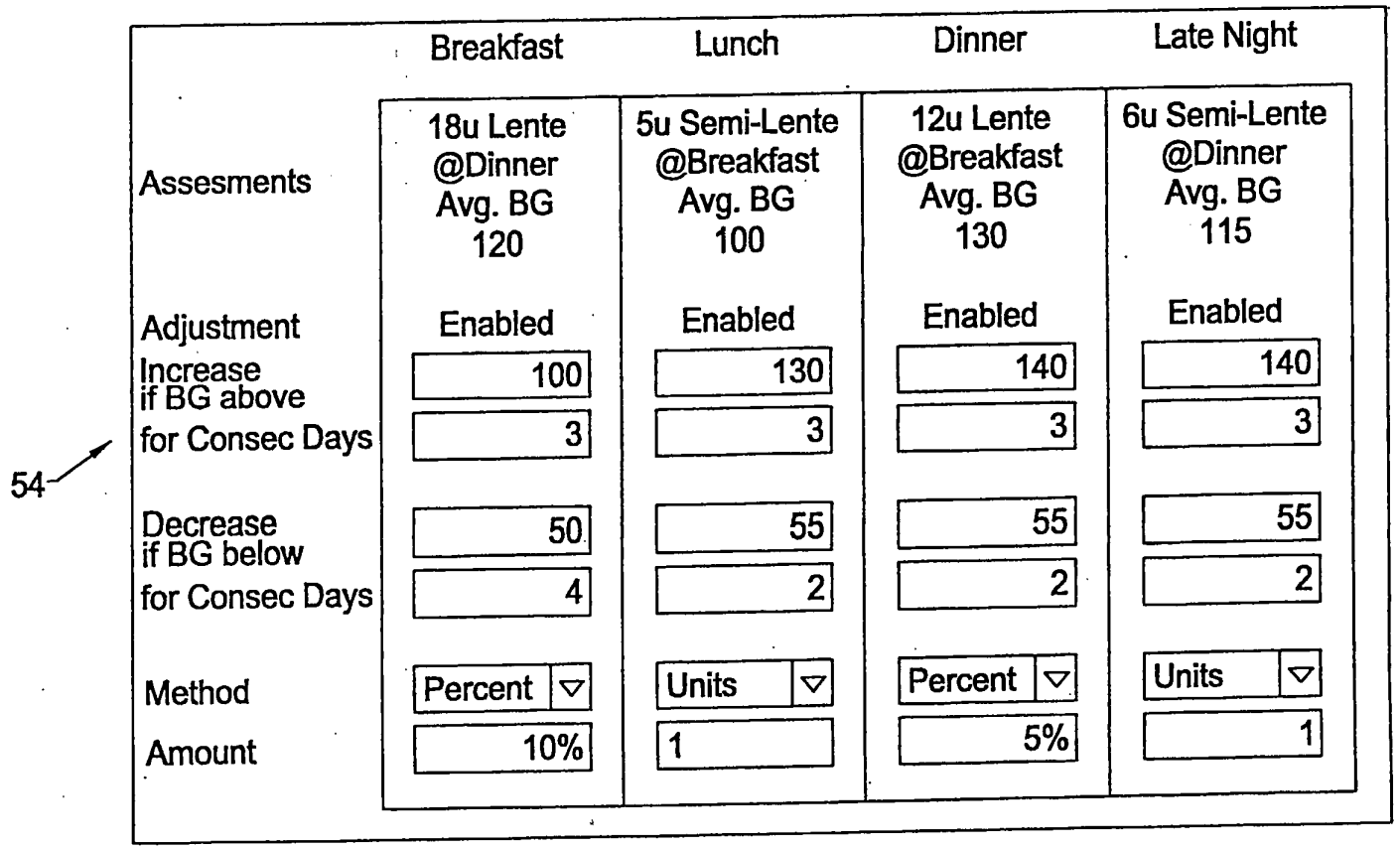

Breakfast
Lunch
Dinner
Late Night
Assesments
18u Lente @Dinner Avg. BG 120
5u Semi-Lente @Breakfast Avg. BG 100
12u Lente @Breakfast Avg. BG 130
6u Semi-Lente @Dinner Avg. BG 115
Adjustment
Enabled
Enabled
Enabled
Enabled
Increase if BG above
100
130
140
140
for Consec Days
3
3
3
3
Decrease if BG below
50
55
55
55
for Consec Days
4
2
2
2
Method
Percent
Units
Percent
Units
Amount
10%
1
5%
1
54

FIG. 11.

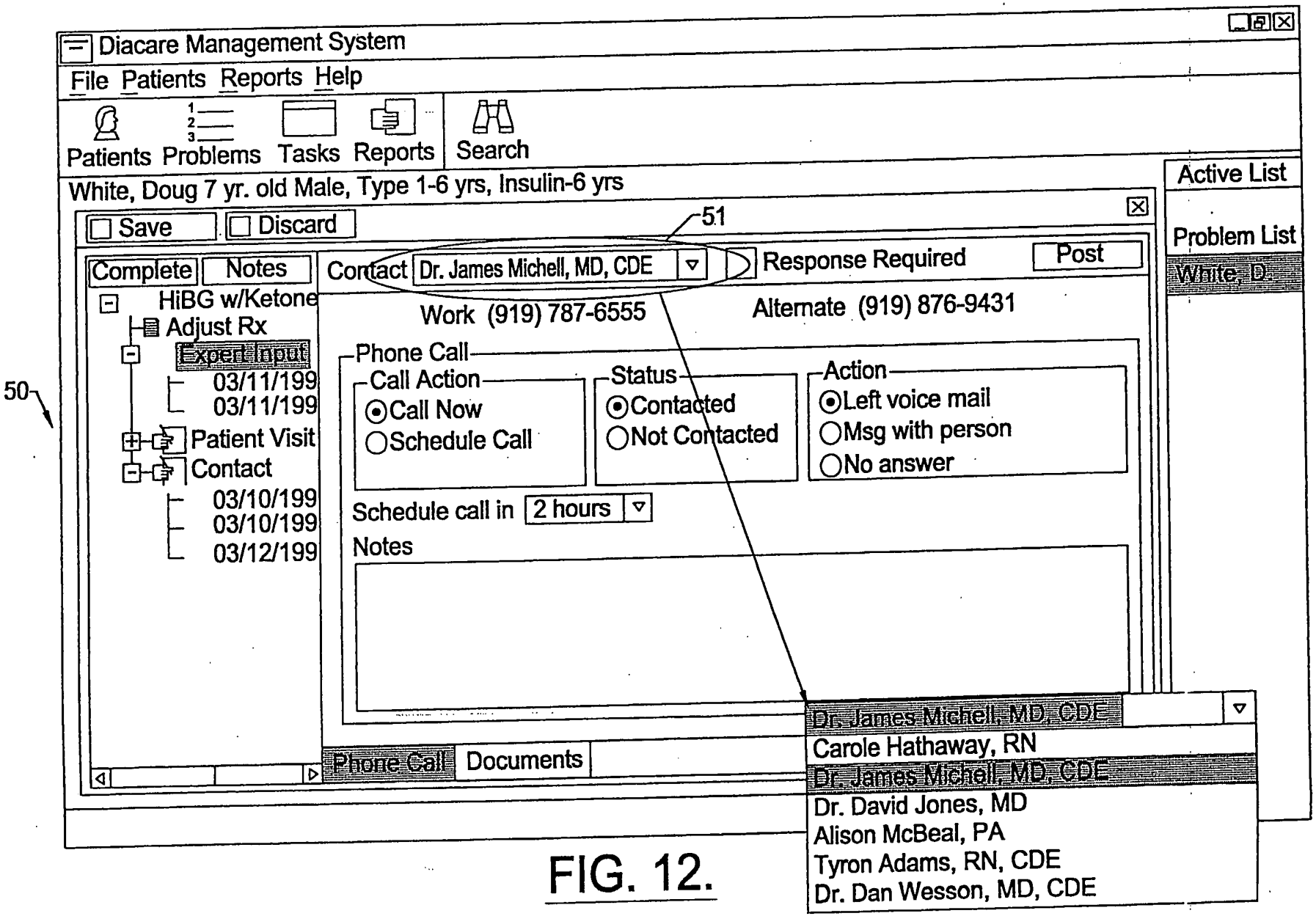

Diacare Management System
File Patients Reports Help
Patients Problems Tasks Reports Search
White, Doug 7 yr. old Male, Type 1-6 yrs, Insulin-6 yrs
Active List
Problem List
White, D.
Save
Discard
51
Complete
Notes
Contact
Dr. James Michell, MD, CDE
Response Required
Post
HiBG w/Ketone
Adjust Rx
Expert Input
03/11/199
03/11/199
Patient Visit
Contact
03/10/199
03/10/199
03/12/199
Work (919) 787-6555
Alternate (919) 876-9431
Phone Call
Call Action
Call Now
Schedule Call
Status
Contacted
Not Contacted
Action
Left voice mail
Msg with person
No answer
Schedule call in
2 hours
Notes
Phone Call
Documents
Dr. James Michell, MD, CDE
Carole Hathaway, RN
Dr. James Michell, MD, CDE
Dr. David Jones, MD
Alison McBeal, PA
Tyron Adams, RN, CDE
Dr. Dan Wesson, MD, CDE
50

FIG. 12.

00770 2608860

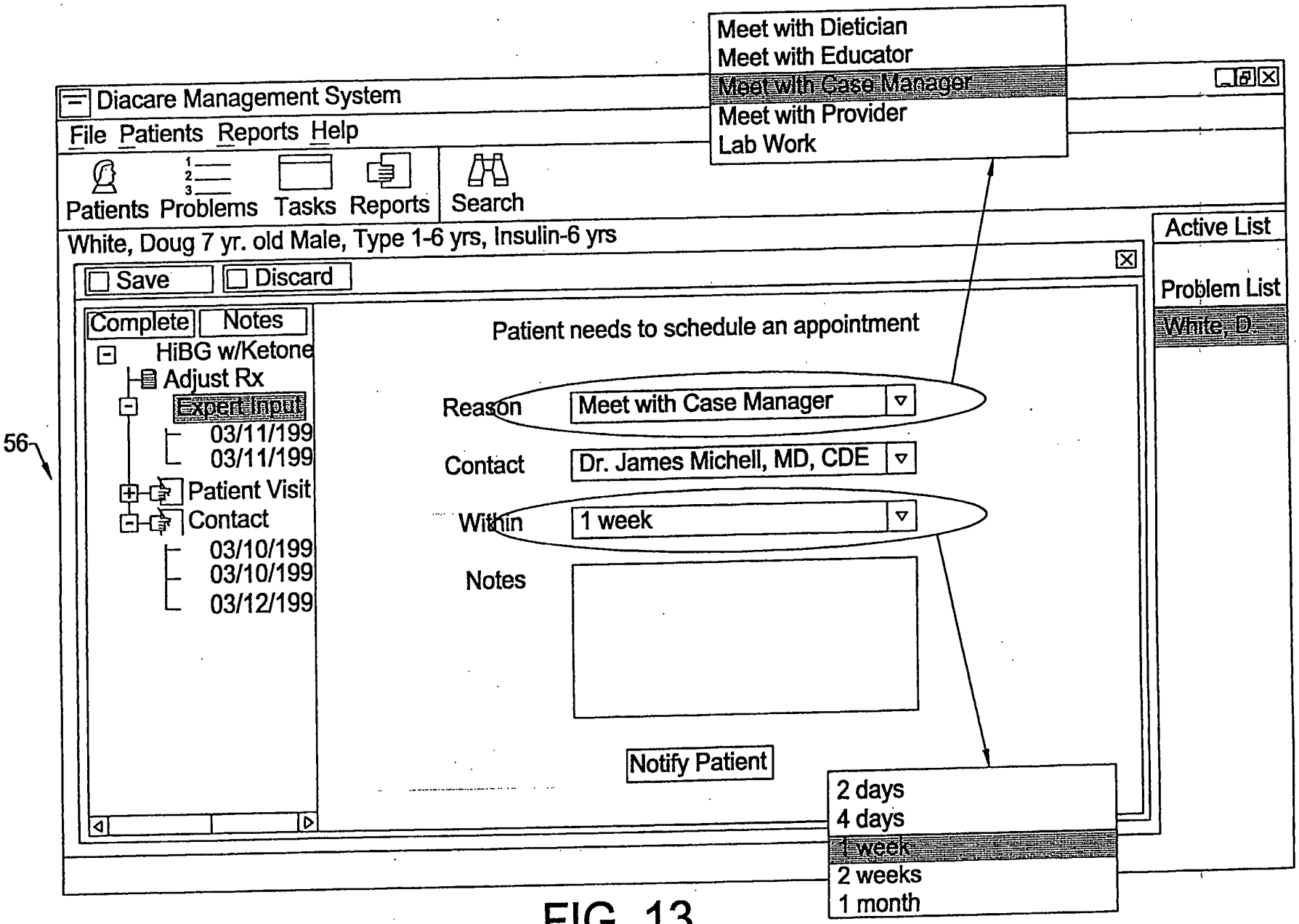


FIG. 13.

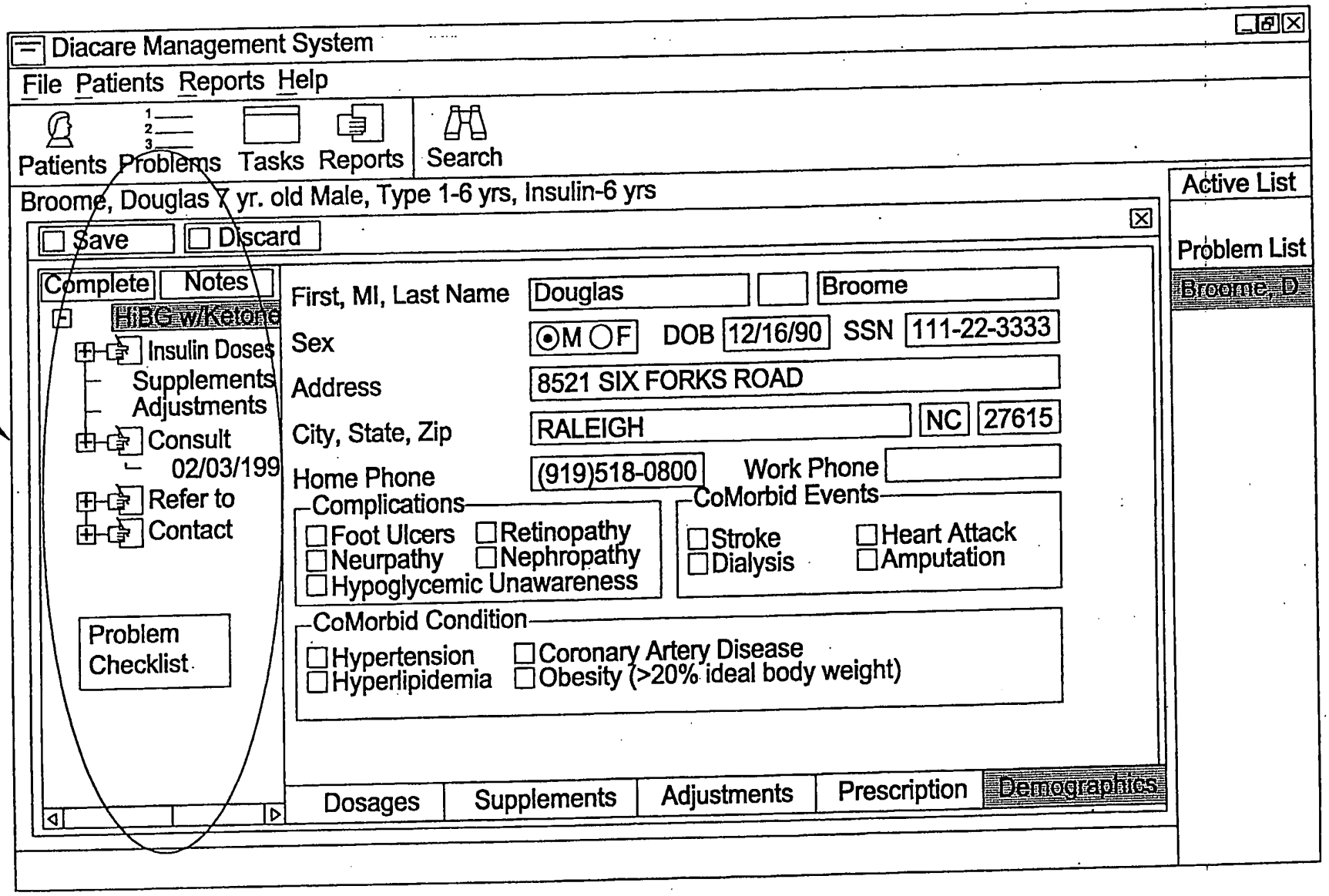

Diacare Management System
File Patients Reports Help
Patients Problems Tasks Reports Search
Broome, Douglas 7 yr. old Male, Type 1-6 yrs, Insulin-6 yrs
Save
Discard
Complete
Notes
HiBG w/Ketone
Insulin Doses
Supplements
Adjustments
Consult
02/03/199
Refer to
Contact
Problem Checklist
58
First, MI, Last Name
Douglas
Broome
Sex
M F
DOB
12/16/90
SSN
111-22-3333
Address
8521 SIX FORKS ROAD
City, State, Zip
RALEIGH
NC
27615
Home Phone
(919)518-0800
Work Phone
Complications
Foot Ulcers
Retinopathy
Neurpathy
Nephropathy
Hypoglycemic Unawareness
CoMorbid Events
Stroke
Heart Attack
Dialysis
Amputation
CoMorbid Condition
Hypertension
Coronary Artery Disease
Hyperlipidemia
Obesity (>20% ideal body weight)
Dosages
Supplements
Adjustments
Prescription
Demographics
Active List
Problem List
Broome, D

FIG. 14.

Fig. 15

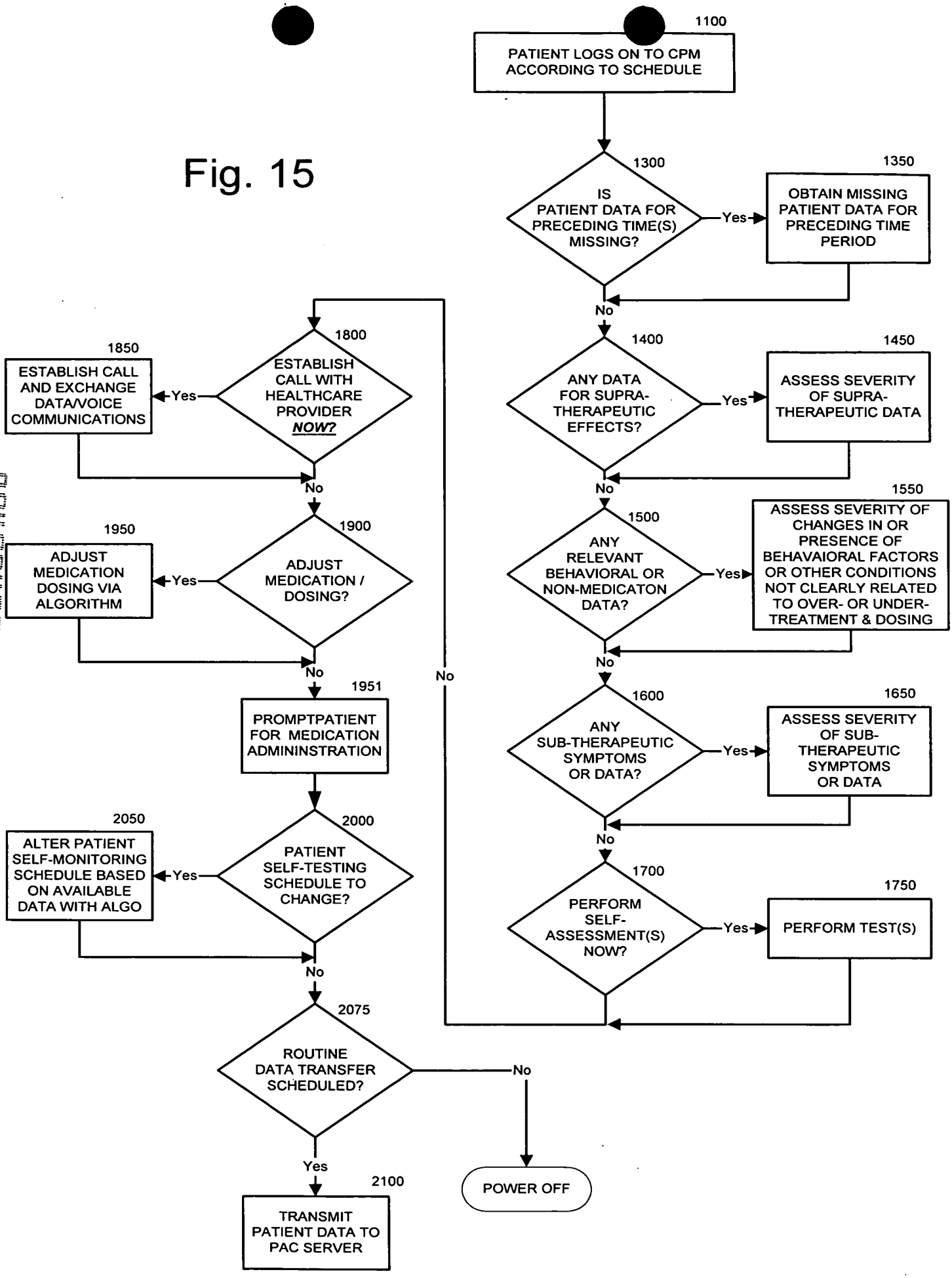
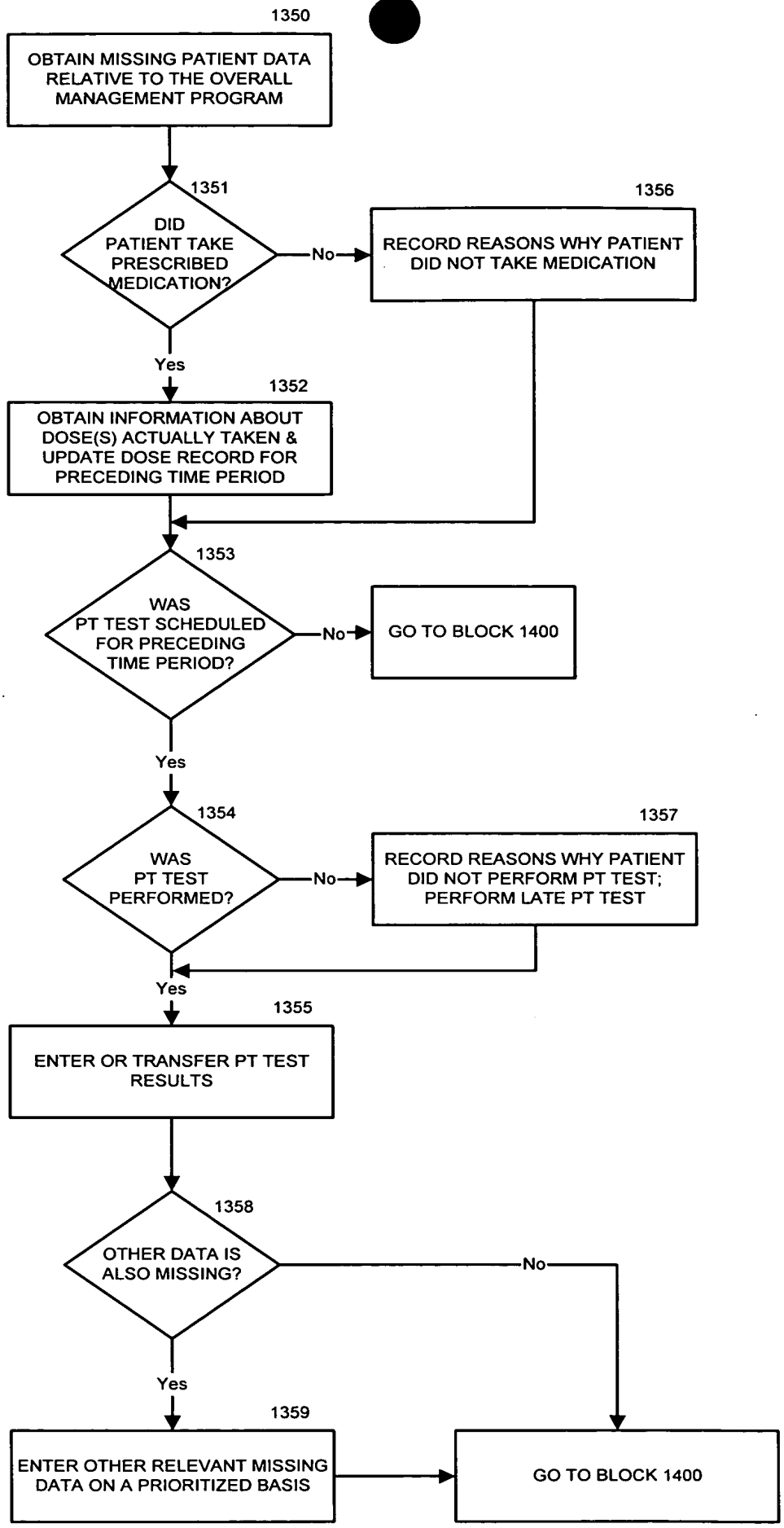

1100
PATIENT LOGS ON TO CPM ACCORDING TO SCHEDULE
1300
IS PATIENT DATA FOR PRECEDING TIME(S) MISSING?
Yes
1350
OBTAIN MISSING PATIENT DATA FOR PRECEDING TIME PERIOD
No
1400
ANY DATA FOR SUPRA-THERAPEUTIC EFFECTS?
Yes
1450
ASSESS SEVERITY OF SUPRA-THERAPEUTIC DATA
No
1500
ANY RELEVANT BEHAVIORAL OR NON-MEDICATON DATA?
Yes
1550
ASSESS SEVERITY OF CHANGES IN OR PRESENCE OF BEHAVAIORAL FACTORS OR OTHER CONDITIONS NOT CLEARLY RELATED TO OVER- OR UNDER-TREATMENT & DOSING
No
1600
ANY SUB-THERAPEUTIC SYMPTOMS OR DATA?
Yes
1650
ASSESS SEVERITY OF SUB-THERAPEUTIC SYMPTOMS OR DATA
No
1700
PERFORM SELF-ASSESSMENT(S) NOW?
Yes
1750
PERFORM TEST(S)
No
1800
ESTABLISH CALL WITH HEALTHCARE PROVIDER NOW?
Yes
1850
ESTABLISH CALL AND EXCHANGE DATA/VOICE COMMUNICATIONS
No
1900
ADJUST MEDICATION / DOSING?
Yes
1950
ADJUST MEDICATION DOSING VIA ALGORITHM
No
1951
PROMPTPATIENT FOR MEDICATION ADMININSTRATION
2000
PATIENT SELF-TESTING SCHEDULE TO CHANGE?
Yes
2050
ALTER PATIENT SELF-MONITORING SCHEDULE BASED ON AVAILABLE DATA WITH ALGO
No
2075
ROUTINE DATA TRANSFER SCHEDULED?
Yes
2100
TRANSMIT PATIENT DATA TO PAC SERVER
No
POWER OFF

Fig. 16



Docket No. 2003P03209US

Document: 2006P03791US

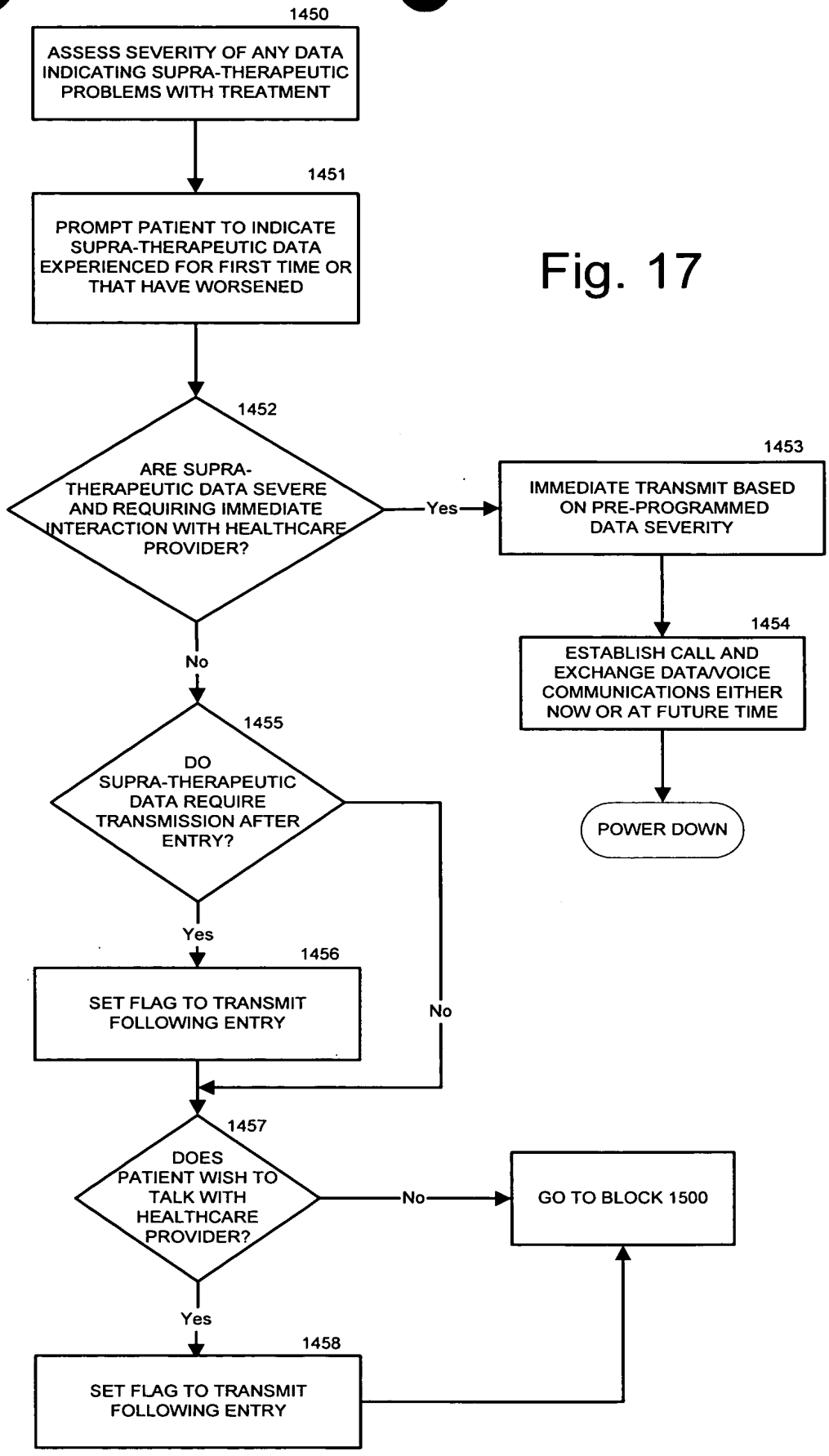


Fig. 17

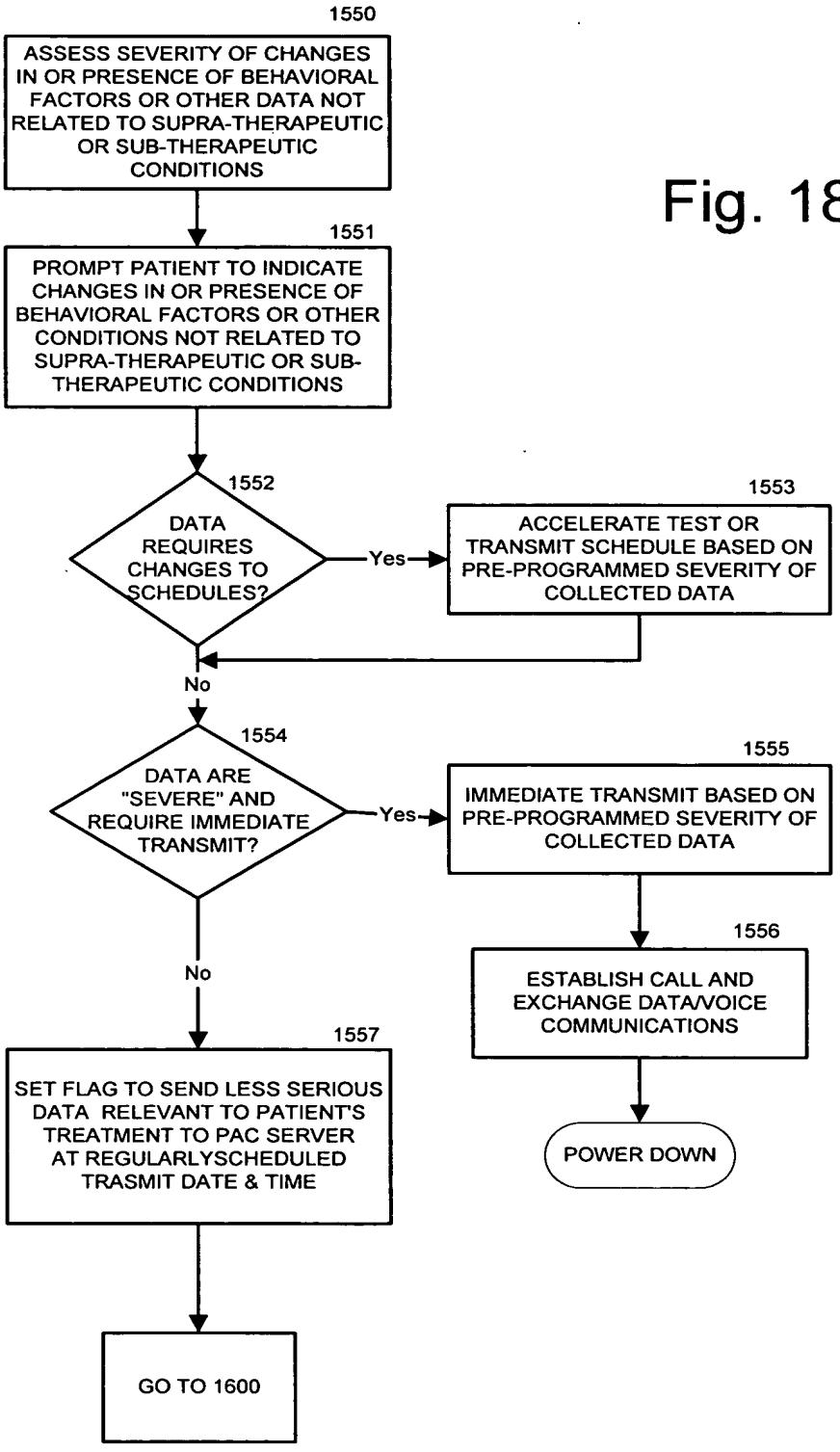


Fig. 18

0074630 :ed 20-Sep-04

DOCKET NO: 76408-6

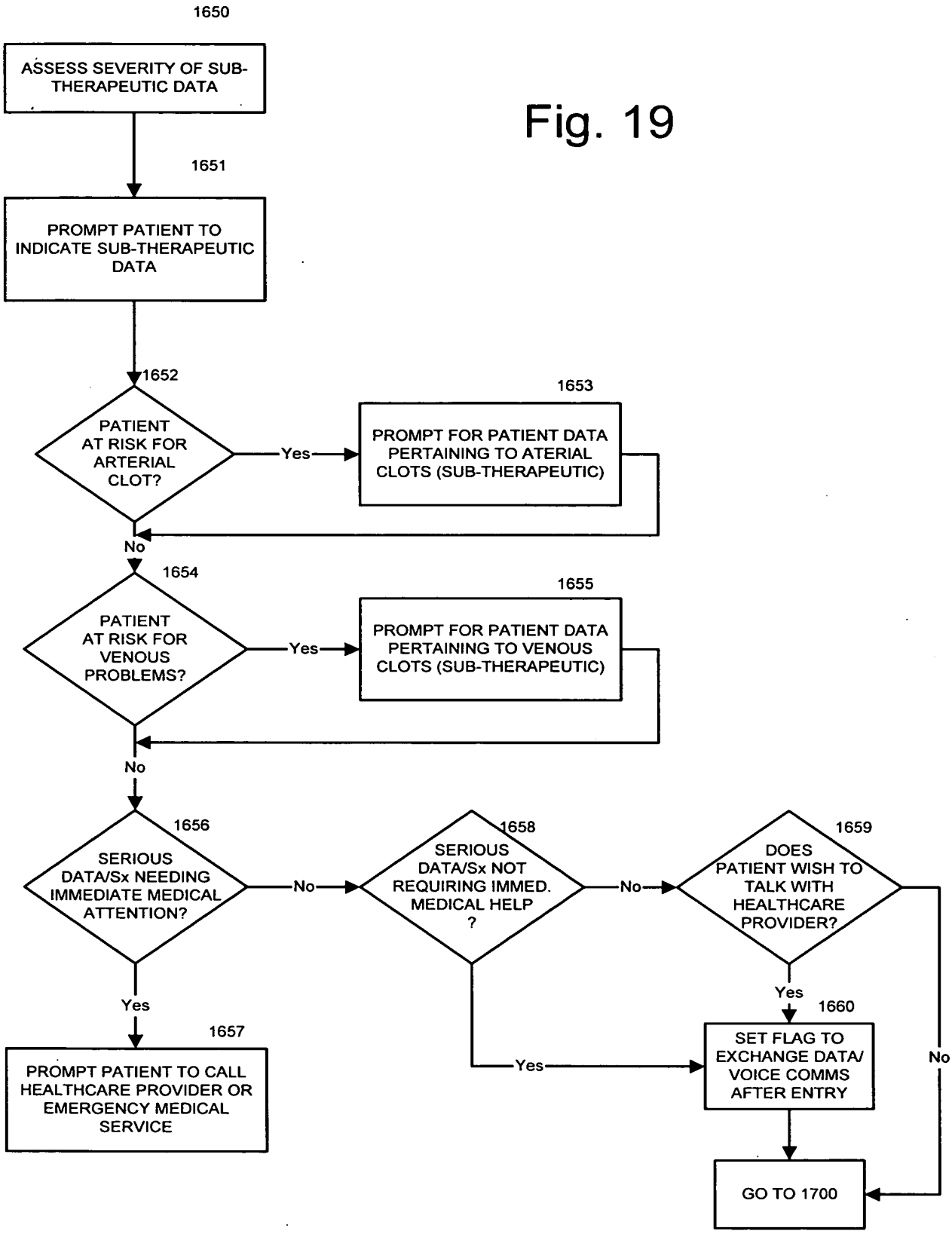



Fig. 19